

### **REMARKS**

On page 2 of the Office Action, the Examiner issued a three-way restriction requirement pursuant to 35 USC §§ 121 and 372. The restriction divided the claims into the following allegedly distinct inventions: Group I drawn to "a process for producing actinol from ketoisophorone, which comprises contacting ketoisophorone with a recombinant microorganism or mutant thereof, wherein the microorganism comprises levodione reductase gene (cellular method)," containing claims 1-8; Group II drawn to "a process for producing actinol from ketoisophorone, which comprises contacting ketoisophorone with cell free extract of a recombinant microorganism wherein the microorganism comprises levodione reductase gene (in vitro method)," comprising claims 1-8; and Group III drawn to "a microorganism or mutant thereof comprising levodione reductase gene," comprised of claims 9-11. (Paper No. 20061113 at 2.)

Applicants respectfully traverse the restriction.

In making the restriction, the Examiner asserted that "Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features." (Paper No. 20061113 at 2.) The Examiner conceded that the three groups contain a single technical feature - "they all relate to a polynucleotide encoding a polypeptide levodione reductase." (*Id.* at 2-3.) The Examiner asserted, however, that "this common technical feature is not a 'special technical feature' as defined by PCT Rule 13.2 as it does not define a contribution over the art." (*Id.* at 3.) The Examiner then asserted that Yoshisumi discloses "a DNA encoding a levodione reductase gene (*Corynebacterium aquaticum* lvr gene for levodione reductase, complete cds, GenBank Accession No.

AB04262, created 10/12/2001) which is known in the art.” (*Id.*) The Examiner then concluded that “a DNA encoding a levodione reductase protein does not make [a] contribution over the prior art.” (*Id.*)

In addition, the Examiner asserted that “the products of Groups III do not share a special common structural and functional feature while, the methods of Groups I and II do not use the same reagents or produce the same results.” (*Id.*) The Examiner further asserted that “the methods of Groups I and II do not comprise all of the methods for making or using the products of Group II.” (*Id.*) The Examiner then concluded that “Groups I-III are not so linked by the same or a corresponding special technical feature as to form a single general inventive concept.” (*Id.*)

Moreover, the Examiner asserted that “[t]he methods of Groups I and II do not have unity of invention with each other as each method[] comprises unrelated steps, use different products and/or produce different effects.” (*Id.*)

According to the MANUAL OF PATENT EXAMINING PROCEDURE (MPEP), the PCT RULES, and the GUIDELINES FOR AUTHORITIES AND OFFICES: PCT INTERNATIONAL SEARCH AND PRELIMINARY EXAMINATION GUIDELINES (“Guidelines”) Chapter 10 propagated by the World Intellectual Property Organization (WIPO), if claims share a common special technical feature, they have unity of invention and should be examined together.

PCT Rule 13.2 defines the manner in which unity of invention may be satisfied:

*Circumstances in Which the Requirement of Unity of Invention Is to Be Considered Fulfilled:* Where a group of inventions is claimed in one and the same international application, the requirement of unity of invention referred to in

Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression **"special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.** (Emphasis added.)

Likewise, MPEP § 1893.03(d) addresses Unity of Invention under the PCT. (8<sup>th</sup> ed. Rev. 5, August 2006, pp. 1800-199 - 1800-201.) Generally, unity of invention is found when the claims share a single general inventive concept.

**A group of inventions is considered linked to form a single general inventive concept where there is a technical relationship among the inventions that involves at least one common or corresponding special technical feature.** The expression special technical features is defined as meaning those technical features that define the contribution which **each claimed invention, considered as a whole, makes over the prior art.** For example, a corresponding technical feature is exemplified by a key defined by certain claimed structural characteristics which correspond to the claimed features of a lock to be used with the claimed key. Note also the examples contained in Chapter 10 of the International Search and Preliminary Examination Guidelines which can be obtained from WIPO's web site ([www.wipo.int/pct/en/texts/gdlines.htm](http://www.wipo.int/pct/en/texts/gdlines.htm)). (MPEP § 1893.03(d) at p. 1800-200.) (Emphasis added.)

To summarize, the MPEP, PCT Rules, and Guidelines from WIPO indicate that claims fulfill the requirement of unity of invention if they share a single special technical feature that define a contribution over the prior art.

The three groups into which the Examiner has divided the claims clearly share a technical feature:

Group I to a process for producing actinol from ketoisophorone employing **a recombinant microorganism** obtainable by transforming a host microorganism ... which is capable of reducing ketoisophorone to levodione with a levodione reductase gene;

Group II to a process for producing actinol from ketoisophorone employing a cell-free extract from **a recombinant microorganism** obtainable by transforming a host microorganism ... which is capable of reducing ketoisophorone to levodione with a levodione reductase gene: and

Group III to **a recombinant microorganism** obtainable by transforming a host microorganism ... which is capable of reducing ketoisophorone to levodione with a levodione reductase gene.

Thus, the shared technical feature is a recombinant microorganism having the capability of reducing ketoisophorone to levodione and expressing the levodione reductase gene. When each claimed invention is considered as a whole, as required by the Guidelines, the Examiner's assertion that the shared technical feature is a polynucleotide encoding a polypeptide levodione reductase is clearly erroneous. This polynucleotide is recited in the claims only as the gene with which the host microorganism is transformed. Because the Examiner has not restricted the claims based on what they recite as a whole, the restriction has not even asserted that what is claimed lacks of invention.

Simply, put the Examiner has not asserted, much less provided evidence that, the shared technical feature - a recombinant microorganism having the capability of reducing ketoisophorone to levodione and expressing the levodione reductase gene - does not define a contribution over the prior art. For this reason alone, the restriction is both legally and factually deficient and should be withdrawn.

Even if the Examiner had considered the share technical feature actually recited by the claims, the restriction would not be properly made. The document cited by the Examiner does not disclose the shared technical feature. Yoshisumi discloses

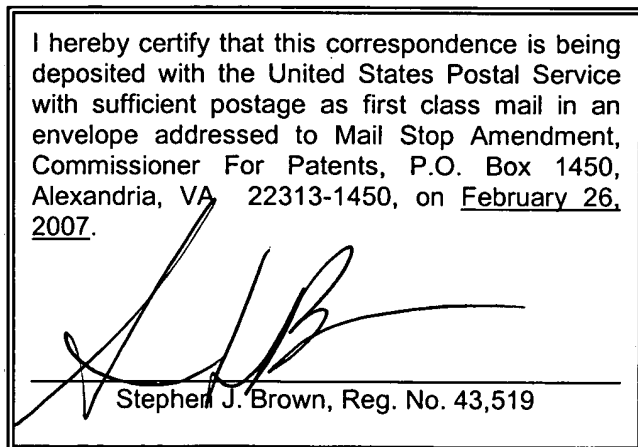
expression of a gene encoding "monovalent cation-activated levodione reductase from *Corynebacterium aquaticum* M-13" in *Escherichia coli*. Yoshisumi also discloses the polynucleotide sequence of the levodione sequence.

However, that is not what is recited by the claims. The claims recite a recombinant microorganism having ***the capability of reducing ketoisophorone to levodione and expressing the levodione reductase gene***. Yoshisumi simply does not disclose a microorganism that is capable of reducing ketoisophorone to levodione.

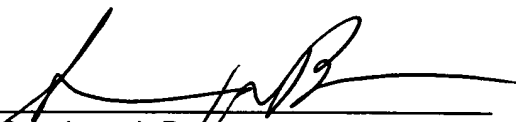
Accordingly, the Examiner has not, and indeed cannot, demonstrate that the technical feature shared by the instant claims is disclosed in Yoshisumi. For this additional reason, the restriction is factually deficient and should be withdrawn.

Without conceding the propriety of the Restriction Requirement, in accordance with restriction practice, the subject matter of Group I (Claims 1-8 (cellular method)) is hereby elected for prosecution with traverse.

Accordingly, withdrawal of the restriction requirement and examination of all claims are respectfully requested. If the Examiner has any questions regarding this paper, please contact the undersigned attorney.



Respectfully submitted,

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